We commend Kearns et al. for their compelling study demonstrating non-inferiority of spinal morphine to fasica iliaca block (FIB) [1]. We would like to invite the authors to comment on some further questions we have about this paper.

Firstly, nonsteroidal anti-inflammatory drugs (NSAIDs) are well known to be opioid-sparing, reducing the consumption of morphine by 30-50% [2]. Do the authors have data on any difference between treatment groups pre- and postoperatively in NSAID consumption?

Secondly, the authors reported a non-significant ($p=0.1464$, Fishers exact test) difference in preoperative paracetamol consumption between treatment groups. Given that pain is a prominent feature prompting hip arthroplasty, could the authors comment on whether relative changes in pain scores might have been more appropriately reported than absolute pain scores?

Finally, the authors suggest that a fascia iliaca block has a low complication rate, justifying the use of sham fascia iliaca blocks. However, in their study there was one incidence of temporary femoral nerve palsy (1 in 54). The sensory, motor and/or functional effects are not described, but this complication is important in a group of patients where a key aim of the surgical intervention is ambulation. Given that FIB does not offer any analgesic advantage (or perhaps even any analgesia [4]) over spinal morphine for hip arthroplasties, do the authors consider FIB to be too risky for hip patients? Also, if there is risk but no clear benefit of fascia iliaca for hip arthroplasty, do the authors think it was justified to use sham fascia iliaca blocks in this study?

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We thank Dr Haque and Fregene for their interest in our study.

As stipulated in our protocol,[1] patients taking NSAIDs pre-operatively continued to take these medications. No NSAIDs were commenced de novo in either treatment group during the study period. Data relating to NSAID use were not recorded and unfortunately we cannot provide this additional information.

The difference in pre-operative paracetamol consumption referred to the pre-medicant dose prescribed as part of the study protocol and not patients' usual medications. Unfortunately, not all patients received pre-operative paracetamol. The staff members who were responsible for administering the paracetamol had no knowledge of the treatment allocation and therefore any omissions were entirely random and should have affected each group equally. In the spinal morphine group, 64.7% of patients received pre-operative paracetamol while in the fascia ililaca group, this was slightly greater at 78.8% (p 0.17). All patients were prescribed regular paracetamol post-operatively. Whilst more patients in the fascia iliaca group received paracetamol pre-operatively, it seems unlikely that this would have significantly altered the results of the study. As patients in the fascia iliaca group had inferior analgesia despite the above theoretical advantage, this reinforces the result of the primary outcome further. We did not collect pain scores pre-operatively as these scores would have related to patients' underlying hip pathology rather than the post-surgical pain they experienced after surgery. As the study was randomised, we would not have expected significant differences between groups for pre-operative pain scores.

We agree that any neuropraxia is a serious adverse event and reported this as such. The patient in this case made a full recovery. The incident of femoral nerve palsy was discussed at length with the surgical team who did not consider it likely to have resulted from the study intervention. The incidence of surgery related femoral nerve palsy is reported as 0.1-2.4% with a mean of 0.8%.[2] It is therefore difficult in practice to establish whether surgery or anaesthesia is causative. The fascia iliaca block is considered a relatively low risk procedure and is approved for use by non-medical practitioners in National guidelines.[3] Any patient undergoing a nerve block should be counselled regarding the risks and benefits in each case.

The issue of sham blocks remains controversial. We accept that the fascia iliaca block is not without risk and patients were informed and consent obtained for the possibility of being administered a sham nerve block. We ensured that the study underwent extensive peer review via grant applications and publication of the protocol.[1] It has been suggested that the use of any sham treatment be evaluated using the "SHAM tool".[4] This aims to establish and minimise any risk of harm to the patient. This tool was first published in 2011, and unfortunately was not available at the time of our study being designed and undergoing ethical review (October 2010). However, in light of the SHAM recommendations, we would not use sham

blocks in future study designs.

Finally, the role of FIB as an adjunct to spinal morphine pre-operatively for THR has not been investigated and more information is required before making any firm recommendations.

References

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